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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/620,924	07/16/2003	Song Luo	114871-037	9378

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MARSHALL, GERSTEIN & BORUN LLP
233 S. WACKER DRIVE, SUITE 6300
SEARS TOWER
CHICAGO, IL 60606

EXAMINER

HORLICK, KENNETH R

ART UNIT	PAPER NUMBER
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1637

DATE MAILED: 02/16/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 10/620,924	Applicant(s) LUO ET AL.	
	Examiner Kenneth R. Horlick	Art Unit 1637	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 71-119 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 71-119 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 16 July 2003 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. ____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. ____. |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date <u>6/18/04 (5 pages)</u> . | 6) <input type="checkbox"/> Other: ____. |

1. The specification is objected to because of the following informalities:
 - a) the continuation information must be updated to indicate issue of the parent '220 application as U.S. Patent No. 6,649,347;
 - b) claim 80 is lacking a period at the end;
 - c) claim 74 has two steps labeled "c".
2. The title of the invention is not descriptive. A new title is required that is clearly indicative of the invention to which the claims are directed. A key feature of the claimed methods would appear to be the use of strand-specific methylation sensitive restriction enzymes and nick translation; it is suggested that this be incorporated into the title.
3. Applicant is reminded of the proper content of an abstract of the disclosure.

A patent abstract is a concise statement of the technical disclosure of the patent and should include that which is new in the art to which the invention pertains. If the patent is of a basic nature, the entire technical disclosure may be new in the art, and the abstract should be directed to the entire disclosure. If the patent is in the nature of an improvement in an old apparatus, process, product, or composition, the abstract should include the technical disclosure of the improvement. In certain patents, particularly those for compounds and compositions, wherein the process for making and/or the use thereof are not obvious, the abstract should set forth a process for making and/or use thereof. If the new technical disclosure involves modifications or alternatives, the abstract should mention by way of example the preferred modification or alternative.

The abstract should not refer to purported merits or speculative applications of the invention and should not compare the invention with the prior art.

Where applicable, the abstract should include the following:

- (1) if a machine or apparatus, its organization and operation;
- (2) if an article, its method of making;
- (3) if a chemical compound, its identity and use;
- (4) if a mixture, its ingredients;

(5) if a process, the steps.

Extensive mechanical and design details of apparatus should not be given.

4. The following is a quotation of the second paragraph of 35 U.S.C. 112:
The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 71-116 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

A) Claims 71-73 are confusing because they depend from canceled claims 1 and 56. Clarification is required.

B) Claims 74-116 are confusing because it cannot be determined what action(s) is encompassed by the last "detecting" step. It is submitted that essential subject matter for understanding what method is being claimed is missing from independent claim 74. Based on the specification including Example 2E on pages 72-74, it is suggested that the single "detecting" step be substituted by steps of "purifying nick translation products", "hybridizing the nick translation products with nucleic acids which may comprise centromere sequence", and "screening any hybridizing nucleic acids to identify a centromere nucleic acid sequence". This language is believed to be necessary because the method is based upon detecting methylated sequences regardless of their chromosomal positional origin, and thus hybridizing fragments will not necessarily be derived from a centromere.

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5. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

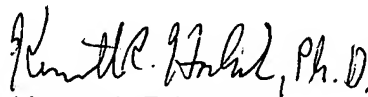
Claims 71-73 and 117-119 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. These claims are drawn to a centromere nucleic acid sequence, a non-human organism, and a progeny of such an organism, defined only in how they are to be prepared, without any physical, chemical, or structural properties whatsoever. Claims of this type are referred to in Technology Center 1600 as "reach-through" claims. It is clear that applicants were not in possession of any and every possible such nucleic acid and organism, which might possibly be prepared at some future point using the disclosed methods, at the time of the invention; thus, these claims clearly do not satisfy the written description requirement. Further, there is no basis on which to search the prior art for the nucleic acids and organisms which are being claimed.

6. Claims 71-119 are free of the prior art, but are rejected for other reasons. No claims are allowable. Regarding the methods of claims 74-116, no prior art has been found teaching or suggesting obtaining or identifying a centromere nucleic acid sequence using the required steps of strand-specific methylation sensitive restriction endonuclease digestion of genomic DNA, nick translation of digested DNA, hybridizing nick-translation product to target nucleic acids, and screening hybridizing nucleic acids to identify centromere sequences. Vongs et al., Bianchi et al., Dellaporta et al., and Mitchell et al. teach that centromere nucleic acid sequences in certain organisms were known to be methylated. De La Torre et al., now made of record as a reference of interest, teaches *in situ* nick translation of human chromosomes after digestion using methylation-sensitive restriction enzymes.

7. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Kenneth R. Horlick whose telephone number is 571-272-0784. The examiner can normally be reached on Monday-Thursday 6:30AM-5:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Benzion can be reached on 571-272-0782. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).


Kenneth R Horlick
Primary Examiner
Art Unit 1637

02/09/06